

chlamydial test from a laboratory. However, contrary to this is the more powerful argument that the great majority, probably approaching 90%, of men with asymptomatic urethritis will not have any significant pathogen. This enormous overdiagnosis of a probable, or possible, sexually transmitted infection (depending on how the clinician seeks to explain the finding to the patient) can therefore lead to considerable unnecessary treatment and, as a result of notifying partners, considerable anxiety and damage to relationships, for both the male patients and their female partners.

The publication of the *Sexually transmitted infection screening and testing guidelines* provides an opportunity to take a consistent approach to STI screening and testing. They also give a basis for calculating future PbR tariffs and help create a level playing

field for the provision of sexual health screening across the country.

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Testing for sexually transmitted infections: a brave new world?

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The sensitivity of nucleic acid amplification tests has made it possible to use non-invasive specimens, such as urine or vaginal swabs, for the diagnosis and screening for major bacterial sexually transmitted infections (STIs). As these specimens can be stored and transported at ambient temperatures, there has been a proliferation of internet-based STI testing services that are advertised as private, safe and confidential. The tests used and the quality of the testing on these internet services are unknown. Simple rapid tests for STIs are also available for purchase from the internet or “over the counter” from pharmacies or stores. Very few countries regulate STI tests sold. Even among the countries that regulate diagnostics for STIs, standards for evaluations are lacking, with the result that product inserts often contain inflated claims of test performance. Preliminary evaluations of some of the rapid chlamydial and gonococcal tests showed good specificity but limited sensitivity. The internet has been recognised in recent years as a new risk environment for STIs in both men and women, and efforts at

internet-based sexual health promotion are hopefully reaching those at risk. However, this trend in STI testing and the lack of regulatory control should raise considerable concern over the potential for false-positive or false-negative results. It remains unclear how many individuals with a positive result would access appropriate treatment and counselling, and notify their sexual partners for testing and treatment. There needs to be closer examination of the implications of these services on STI control programmes.

Imagine a teenager who just discovered that she has vaginal discharge. She has been in two short sexual relationships and has not been consistent with condom use. She is worried but is too scared to tell her parents or her sexual partners. She does not want to go to her family doctor or be seen going to the local clinic. In the privacy of her room, she goes on the internet to find out what she can do. She types in the search term, “testing for STDs”. She looks up the first five sites that come up.

The first site is <http://www.iwannaknow.org>. It is the site of the American

Social Health Association, where she can learn all about the basics of sexually transmitted infections (STIs) and where to get tested. The second site is <http://www.familydoctor.org>, a site put up by the American Academy of Family Physicians. It too gives comprehensive information on STIs, and tips on prevention. The third site is <http://www.4woman.org>, developed by the US Department of Health and Human Services, with information tailored for women who have a disproportionate share of the disease burden of STIs. The fourth and fifth websites are both commercial or sponsored sites, <http://www.mtv.com> and <http://www.coolnurse.com>, with links to educational information on STIs. All these sites give excellent educational information, but they all advise our teenager to go to a doctor or a clinic.

She then changes her search term to “home testing for STDs”. The first site is <http://www.iwantthekit.org>. This is a site set up by the City of Baltimore Department of Health in collaboration with the Johns Hopkins Medical School to encourage women ≥ 14 years of age to get tested for chlamydia. Requests for a chlamydia testing kit can be sent through the internet, email or telephone. A kit can be sent by mail or picked up at a pharmacy or a recreation centre. The kit consists of instructions for self-collection of a vaginal swab, a short questionnaire, a dacron swab and a mailing tube for the swab in a prepaid

Abbreviations: NAAT, nucleic acid-amplified test; SDI, World Health Organization Sexually Transmitted Diseases Diagnostics Initiative; STI, sexually transmitted infection; WHO, World Health Organization

Table 1 Testing of sexually transmitted infections

Traditional venues	Doctor's office STI clinics Ob/Gyn clinics Family planning
Outreach venues	Schools Youth centres Military units Detention centres Hospitals—emergency departments Pharmacies

Ob/Gyn, obstetrics and gynaecology; STI, sexually transmitted infection.

envelope for the specimen to be mailed to the Johns Hopkins University STD Laboratory. Between August 2004 and January 2005, >1100 kits were mailed out and 400 were returned for testing.¹ More than 50% of those who sent a vaginal swab for testing were <25 years of age. Chlamydia was detected in 10% and gonorrhoea in 1% of samples. More than 86% of respondents said they would use this internet programme again.

TAKING STI TESTING OUT OF THE DOCTOR'S OFFICE OR CLINIC

Advances in diagnostic technology have resulted in a new generation of STI tests and nucleic acid-amplified tests (NAATs), which not only offer high sensitivity and specificity but also exquisite sensitivity, making it possible to use non-invasive or minimally invasive specimens such as urine, vulval or vaginal swabs.^{2–6} Unlike culture, these tests do not require specimens to be viable. Thus, specimens can be transported and stored at ambient temperatures. This has revolutionised STI testing and screening in that these activities can now be conducted at venues not previously thought possible. For women, the use of vaginal swabs means STI testing is no longer tied to a pelvic examination for the collection of an endocervical swab. Studies have shown no difference in detection rates between self-collected and doctor-collected vaginal swabs.^{7–8}

Thus, instead of waiting for individuals to come to a doctor's office or an STI or family planning clinic, outreach STI screening programmes have been conducted with specimens collected from street youths and army recruits, and at schools, detention centres, prisons or hospital emergency departments, and sent to the laboratory for NAAT (table 1).^{9–13} Other innovative approaches explored were postal and pharmacy-based screening for *Chlamydia trachomatis*.^{14–17} A sample of asymptomatic men and women aged 20–24 years randomly selected from a population registry in Sweden were approached to participate in a postal

chlamydial screening programme. Those who agreed sent urine specimens obtained at home to a laboratory for NAAT. At a participation rate of 55%, this postal screening approach would be cost effective if *C. trachomatis* prevalence exceeds 5.1% in women and 12.3% in men.¹⁴ In a pharmacy-based study, women aged 15–29 years who bought contraceptives at a pharmacy were offered a chlamydia screening kit. Although only 27% of those offered the kit mailed a home-collected urine specimen to a laboratory for NAAT, the positivity rate of 9% overall and 14% among 15–24-year olds suggest that such a programme could reach a high-risk population.¹⁷ There is potential for pharmacies to offer more STI services than syndromic management for STIs.¹⁸

Our teenager is not entirely comfortable with public sector services, as the local public health department may decide to track down her sexual contacts if she has a positive result, or worse, send a public health nurse to her home. And what if our teenager does not live in the US, or she prefers a more confidential type of service? She found her answer after a further search for STI tests on the internet.

STI TESTING SERVICES ON THE INTERNET

A whole array of options are available for STI testing, from paying for private, confidential STI testing services advertised on the internet to purchasing a rapid STI test online for home use (table 2). In response to the syphilis outbreak in the city of San Francisco, California, USA, the Department of Health launched an online syphilis testing service at <http://www.stdtest.com> in June 2003. This service is anonymous and is provided free of charge. Anyone interested in syphilis screening can fill out a requisition form online, print it and take it to one of several designated laboratories in San Francisco for blood to be drawn. The results are then available confidentially through the internet with the number of the requisition form and a password. The names and locations of those who

use this service are not linked to the city's STI programme database and are erased daily to ensure confidentiality.¹⁹

If she needs more privacy, services are available, where on payment online with a credit card, a specimen collection kit can be mailed to her home in a plain envelope or she can pick it up at the nearest pharmacy (table 2). All she has to do then is to follow the instructions provided for specimen collection, and send the specimen back in a prepaid envelope for testing. Two days to a week later, she can check for her results on the internet with a secret password. A wide range of testing services and pricing are available, ranging from US\$2.50–89.50 for a chlamydia or gonorrhoea test to US\$159 for a herpes culture (table 3).

Other variations for STI services include sending for a test kit that can be used at home. This involves self-interpretation of test results, which may pose difficulties. Another site offers a walk-in STI testing service without a consultation with a doctor. The same site also sells STI test kits to be used at home. For an additional £25, a telephone consult with a doctor can be added to these home test kits. An internet-independent option is to purchase a test kit over the counter at a store for testing at home. Rapid STI tests are now commercially available through stores, including pharmacies, sex shops and other commercial venues in different parts of the world.

Our teenager is then faced with what STI services and which vendor she should choose. Most of the sites do not specify what tests they use, and there is no assurance of the quality of the testing. She prefers the rapid tests with which she can get instant answers, but are these tests as good as the manufacturers' claims of 98–99.99% accuracy?

RAPID TESTS FOR STIs

Recent progress in rapid detection technology has led to the development of simple rapid STI tests that can be performed in a few steps without any equipment and give a visual result in <30 min.^{20–22} The use of rapid tests allows immediate treatment to prevent the development of long-term sequelae and to interrupt onward transmission of the infection. Counselling and partner notification can also be initiated without delay. Even though most rapid tests tend to have lower sensitivity than laboratory-based tests, studies have shown that rapid tests can lead to a larger number of infected patients being treated than more sensitive laboratory-based tests in settings where patients are unlikely or unable to return for test results and treatment.^{23–24} The pros and cons of when a rapid test is useful are setting specific and should be considered

Table 2 Examples of new approaches to STI testing

	Origin	Test kits	Specimen collection	Testing	Test result
1	Web: fill in and print requisition at home and go to clinic	Not applicable	Clinic	Clinic	Received at home by mail or internet
2	Web: request kit	Pick up at pharmacy or recreation centre	Home	Mail specimen to clinic for testing	Received at home by mail or internet
3	Web: request kit	Mailed to home	Home	Mail specimen to clinic for testing	Received at home by mail or internet
4	Web: request kit	Mailed to home	Home	Home	Own interpretation of results with option for a phone consult
5	Web: request kit	Mailed to home	Home	Home	Own interpretation of results
6	Not applicable	Purchase in a store	Home	Home	Own interpretation of results

STI, sexually transmitted infection.

within the context of local public health programmes.²⁵

Many rapid STI tests are commercially available but in most cases, their performance has not been vigorously evaluated. The World Health Organization Sexually Transmitted Diseases Diagnostics Initiative (SDI) has developed the ASSURED criteria as a benchmark for whether tests address disease control needs: Affordable, Sensitive, Specific, User friendly, Rapid and robust, Equipment-free and Deliverable to end-users. The SDI conducted evaluations of commercially available rapid tests for the major curable bacterial STIs of syphilis, chlamydia and gonorrhoea in its network of laboratory and field sites around the world. Results of these evaluations and of mathematical models to estimate the impact and cost-effectiveness of introducing rapid tests into control programmes will be published in an upcoming special supplement of STI. This will also be

available electronically from STI journal and the SDI web sites (www.who.int/std_diagnostics). Table 4 shows the types of rapid STI tests available and data from the peer-reviewed literature on their performance and operational characteristics.

Rapid tests for chlamydia and gonorrhoea

Rapid tests for the diagnosis of gonococcal infection currently include microscopy performed on a Gram-stained smear of genital discharge from a patient, and several immunoassays for the detection of antigens.²⁶ Rapid chlamydia tests have also been developed as antigen-detection tests.^{27–29} High-affinity antibodies for capturing the antigen are fixed on to nitrocellulose strips. Chlamydial or gonococcal antigen extracted from a patient's specimen binds to the antibodies on the strip and appears as a coloured line. These immunochromatographic strip tests, often

encased in plastic cassettes, do not require any equipment and can give a visual result within 30 min. The major drawbacks are that they are costly, ranging from US\$5 to 90 each, and the processing may be complicated, involving 7–14 steps, which makes the testing difficult to incorporate into a busy clinic routine. Most of the tests have claims of high sensitivity and specificity, but there is limited independent evaluation of their performance and robustness. Studies conducted by the SDI showed that antigen-detection tests for chlamydia and gonorrhoea have sensitivities of 50–70% and specificities of 91–98% compared with NAATs. Test sensitivity falls to <40% if vaginal swabs are used.^{30–32} With improved sensitivity, these tests have the potential to improve the specificity of syndromic management.^{33–35}

Rapid tests for vaginal discharge

Simple rapid tests, requiring only a microscope and a trained microscopist, are available for the diagnosis of vaginal infections. These include wet mount for *T. vaginalis*, and a combination of abnormal vaginal pH and the Whiff test for amines or the identification of clue cells as an indicator of bacterial vaginosis. Bacterial vaginosis can be diagnosed clinically using the Amsel criteria or in the laboratory using the Nugent score, which is based on the proportion of lactobacilli in vaginal flora seen on a Gram-stained smear.^{36–37} Simple rapid tests that detect pH, bacterial enzymes markers on a card format or immunochromatographic strips that detect trichomonal antigens are now commercially available for the diagnosis of vaginal infections.^{38–43} Although easy to use, they are costly and have not been widely validated. Of

Table 3 Test for STIs available from the internet, walk-in clinics or for home use

STI	Target	Specimen	Cost range
<i>Chlamydia trachomatis</i> DNA antigen		Vaginal swab or urine	US\$89.95; £29.95–£45
		Vaginal swab	£2.1–12; US\$6–16
<i>Neisseria gonorrhoeae</i> DNA antigen		Vaginal swab or urine	US\$89.95–£45
		Genital swab	US\$1–\$16
<i>Trichomonas vaginalis</i> Antigen		Vaginal swab	US\$12
Bacterial vaginosis	pH and enzyme markers	Vaginal fluid	US\$19.90/2 or US\$99.50/12
Herpes simplex type 2	Virus culture antibody	Lesion	US\$159.95
		Blood	US\$35
Syphilis	Antibody	Blood	US\$1–£60

STI, sexually transmitted infection.

Table 4 Rapid tests for the diagnosis of sexually transmitted infections and vaginosis

Condition	Type	Target	Specimens	Sensitivity (%)	Specificity (%)	Comments
<i>Chlamydia trachomatis</i> infection	ICS or optical immunoassays	Antigen	Urethral, cervical swabs	50–86	98–100	Performance compared with NAAT or culture; some kits can be used with concentrated urine from men
<i>Neisseria gonorrhoeae</i> infection	Gram stain	Morphology	Urethral, cervical swabs	>90, M 45–65, F	>95, M 90–95, F	Performance compared with culture; requires microscope and technical expertise
	ICS or optical immunoassays	Antigen	Urethral, cervical swabs	50–70	91–99	Performance compared with culture; some kits can be used with concentrated urine from men
<i>Trichomonas</i>	Wet mount	Motile	Vaginal secretions	50–70	99–100	Performance compared with culture; requires microscope
Vaginalis infection	ICS	Trichomonad antigen	Vaginal swab	100	98	Performance compared with culture and wet mount
Bacterial vaginosis	Gram stain	Gram-negative rods	Vaginal swab	NA*	NA*	Requires microscope; scoring standardised (Nugent score)
	Wet mount	Clue cells	Vaginal fluid	38–70	90–95	Performance compared with Nugent score; requires microscope
	Card test	pH and proline aminopeptidase	Vaginal Swab	91	62	Performance compared with Nugent score; 40–59% sensitivity, 92–95% specificity against pH and amine test
	ICS	Sialidase	Vaginal swab	88–91	95	Performance compared with Gram stain
Syphilis	Non-treponemal-specific tests	Antibody	Serum	85–98	90–95	Reagent requires refrigeration; requires centrifuge to separate serum and rotator
	Treponemal-specific tests	Antibody	Serum, plasma or whole blood	85–98	94–100	Do not distinguish between current and past infection
	Dark field microscopy	Motile spirochaete	Lesion material	<50	95–100	Requires microscope; low sensitivity owing to prior application of antiseptic or antibiotic treatment
Herpes simplex virus type 2	ICS	Antibody	Serum	96	98	Performance compared with culture for sensitivity and immunoblot for specificity; US\$35/test

F, female; ICS, immunochromatographic strip; M, male; NAAT, nucleic acid-amplification test.

*Performance uncertain in the absence of consensus reference standard.

Data compiled from Mabey *et al.*,²¹ Suzuki *et al.*,²⁶ Woolley *et al.*,²⁷ Widjaja *et al.*,²⁸ Pate *et al.*,²⁹ Alary *et al.*,³⁰ Benzaken *et al.*,³¹ Yin,³² Myziuk *et al.*,³⁸ Bradshaw *et al.*,³⁹ Wiggins *et al.*,⁴⁰ West *et al.*,⁴¹ Huppert *et al.*,⁴² Unicef/UNDP/World Bank/WHO,⁵⁴ Montoya *et al.*⁶⁵ and Ashley *et al.*⁶¹

interest is a home test for the detection of abnormal vaginal pH, particularly for women in the last trimester of pregnancy as a risk indicator for preterm birth. This is marketed as a test glove in which a small piece of material with a pH indicator has been inserted into the tip of the glove. A colour chart is provided, showing a range of pH values. Pregnant women are advised to check their vaginal pH as often as twice weekly at a cost of £14.99 for 20 test gloves.

Rapid tests for syphilis

The World Health Organization (WHO) estimates that approximately 12 million new cases of venereal syphilis occur worldwide each year, mostly in developing countries where access to sexually transmitted disease laboratory services are limited.⁴⁴ The recent re-emergence of syphilis in the Russian Federation, eastern Europe and China has been associated with social upheaval and is potentially a contributor to burgeoning HIV epidemics in these countries.^{45–46} In North America and western Europe, syphilis has re-emerged as a disease mainly in injecting drug users and men who have sex with men.⁴⁷

Screening for syphilis has traditionally been performed with non-treponemal tests such as the rapid plasma reagin or Venereal Disease Research Laboratory tests, with positive results confirmed by a treponemal test such as the *Treponema pallidum* haemagglutination assay.⁴⁸ Simple, rapid point-of-care treponemal-specific tests that can use whole blood, require minimal training and no equipment, and can be stored at room temperature are now commercially available.⁴⁹ Several of these rapid tests were evaluated by the SDI and others and found to have sensitivities and specificities of 85–98% and 92–98%, respectively, compared with standard treponemal assays.^{50–58} These tests are now available through the WHO Bulk Procurement Scheme for US\$0.19–1 per test (http://www.who.int/std_diagnostics). A disadvantage of these treponemal tests is that they cannot distinguish between active infection and past treated infection, as treponemal antibodies tend to be retained for years.

The affordability and portability of these rapid syphilis tests will allow countries to increase access to antenatal screening to prevent congenital syphilis.

Syphilis in pregnancy is a leading cause of perinatal deaths in developing countries.⁵⁹ A study in Tanzania found that it was responsible for approximately 50% of all stillbirths.⁶⁰ It is estimated that <30% of pregnant women are screened for syphilis in sub-Saharan Africa.^{59–61} A study in Bolivia showed that although 76% of the study population received antenatal care, only 17% were screened for syphilis during pregnancy.⁶² There are many reasons for the failure to provide antenatal screening, but one of the major barriers is that rapid plasma reagin or Venereal Disease Research Laboratory screening requires a laboratory with trained personnel, a source of electricity to run a refrigerator for storing the reagents, a centrifuge to separate serum from whole blood and a shaker to perform the serological tests. Such facilities are often unavailable in primary healthcare settings, hence blood or serum samples have to be transported to regional or central facilities for testing. This often results in lengthy delays or specimens that are lost in transit. When testing is performed off-site, many patients fail to return for their results for a variety of reasons, most often because they are

unable to travel long distances to reach the clinic. The increased access to syphilis screening using rapid tests holds promise for saving babies from stillbirth, facilitating the elimination of congenital syphilis in the developing world and improving syphilis control.

Genital herpes

For genital herpes infections, rapid tests for the detection of antibody to Herpes simplex virus type 2 are available, but they are expensive.⁶³ In view of the lack of control strategies for genital herpes infection in most countries, and the lack of curative treatment, the utility of such tests in disease control is uncertain.

Should we be concerned with the quality of the online STI testing and rapid tests that are sold over the counter? Do they have performance characteristics that make them useful?⁶⁴

LACK OF REGULATORY CONTROL OF DIAGNOSTIC TESTS

The Special Programme for Research and Training in Tropical Diseases housed in WHO conducted a global survey of regulatory practices for in vitro diagnostics in 2001. A questionnaire was sent to all 192 WHO member states to inquire whether in vitro diagnostics, other than those used for blood banking, were regulated in their country and, if so, whether clinical trials were required for regulatory approval. Of the 85 countries that responded, 41 (48%) countries reported that they regulate in vitro diagnostics for infectious diseases, with most of these being developed countries.⁶⁵ Of the 41 countries that regulate diagnostics, 28 (68%) require the submission of clinical trial data, but no standards exist to ensure that the performance of these diagnostics are properly evaluated.⁶⁶ An industrial survey conducted by WHO/Special Programme for Research and Training in Tropical Diseases in 2003 found that companies may spend as little as US\$2000 or as much as US\$2 000 000 on diagnostic trials of different products. Claims of test sensitivity and specificity on product inserts often do not state how many patients were recruited for the evaluations, nor are the study populations well defined. Dossiers submitted to the SDI showed that some diagnostic trials were conducted with as few as 15 patients and with as few as three positive patients (unpublished WHO/SDI data). Of the 24 countries that provided data by disease, 83% regulated diagnostics for HIV, 92% for hepatitis, 42% for STIs and 13% each for tuberculosis and malaria. As a result, STI tests are being sold and used in much of the world without evidence of effectiveness, possibly resulting in

misdiagnosis and in precious health dollars being spent on tests of dubious quality.

Further, what are the implications for home testing in terms of self-interpretation of test results and the lack of counselling and support? How many individuals faced with a positive test result will have access to appropriate treatment and notify their sexual partners for testing and treatment? What are the implications for STI control programmes?

CONCLUSIONS

The WHO estimates that >340 million new cases of curable bacterial STIs (chlamydia, 92 million; gonorrhoea, 62 million; syphilis, 12 million; and trichomonas, 174 million) occur every year, >90% of which occur in settings with no or limited access to STI laboratory services.⁴⁴ Diagnostic tests are important for screening and STI case management, as most infected individuals have mild or no symptoms, and untreated STIs can lead to serious consequences such as chronic pelvic pain, pelvic inflammatory disease, ectopic pregnancy, tubal infertility, cervical cancer and many adverse outcomes of pregnancy. Quality-assured STI testing is a critical component of an effective control programme, as early identification and treatment of those who are infected can avert sequelae and prevent onward transmission. In recent years, the internet has been recognised as a new risk environment for STIs for both men and women.^{67–68} The internet is also an effective vehicle for sexual health promotion.⁶⁹ Although it is important for individuals to take responsibility for their own sexual and reproductive health, the proliferation of internet-based services and the lack of regulation of STI tests should raise considerable concern. These STI services are offering testing to those who are reluctant to access public-sector services because of the stigma associated with STI, like our teenager. With roughly one million new cases of curable STIs occurring worldwide each day, and half of these cases in the young, the burden and psychosocial costs of misdiagnosis for STIs are unthinkable.

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